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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,723	03/18/2004	Lawrence Rosenberg	14647-24 FC	5031
1059	7590	01/05/2006	EXAMINER	
BERESKIN AND PARR 40 KING STREET WEST BOX 401 TORONTO, ON M5H 3Y2 CANADA			AFREMOVA, VERA	
			ART UNIT	PAPER NUMBER
			1651	
DATE MAILED: 01/05/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/802,723	ROSENBERG ET AL.	
	Examiner Vera Afremova	Art Unit 1651	

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 18 March 2004.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-14 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Claims 1-14 are pending and subject to restriction requirement.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to a culture medium with solid matrix and factor(s), classified in class 435, subclass 404, for example.
- II. Claim(s) 6, drawn to a method for making duct-like structures from islets or acinar cells by culturing in a medium with solid matrix and factor(s), classified in class 435, subclass 395, for example.
- III. Claim(s) 7, drawn to a method for islet cell expansion, classified in class 435, subclass 375, for example.
- IV. Claim(s) 8, drawn to a method for producing bipotential cells, classified in class 435, subclass 377, for example.
- V. Claim(s) 9, drawn to a method for treatment of diabetes mellitus by *in situ* induction of differentiation of duct-like cells in insulin-producing cells, classified in class 424, subclass 9.1, for example.
- VI. Claim(s) 10, drawn to a method for treatment of diabetes mellitus by *in vitro* induction of differentiation of duct-like cells in insulin-producing cells, classified in class 424, subclass 93.7, for example.
- VII. Claims 11-13, drawn to a culture medium for islet neogenesis comprising islet neogenesis inducer compound(s), classified in class 435, subclass 405, for example.

VIII. Claim(s) 14, drawn to a method for inducing islet neogenesis by treating duct-like structures with a medium comprising islet neogenesis inducer compound(s), classified in class 435, subclass 384, for example.

The inventions are distinct, each from the other because of the following reasons:

Invention I and Inventions II-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a culture medium with solid matrix and factor(s) can be used for culturing a variety of cells including bone marrow, skin, liver, mucosal epithelium, etc. For example: see US 5,656,721 entire document including col. 3, lines 8-35.

The methods of groups II-VI and VIII are different as claimed and they require different active steps and different structural elements that result in different effects as claimed.

Invention I and Invention VII are distinct because they are drawn to two different products or to different medium compositions that require different components as claimed wherein islet neogenesis inducer(s) including, for example: gastrin, of the group VII medium are not required for the medium of the group I as claimed.

Invention VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case a medium with gastrin can be in vivo administered for stimulation of acid secretion. For example: see US 4,920,129 at col. 14, lines 25-30.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for the other groups, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

January 3, 2006



VERA AFREMOVA

PRIMARY EXAMINER